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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,108	02/13/2002	Christoph Pedain	SCHWP0156US	6951

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EXAMINER	
EDWARDS, PATRICK L	
ART UNIT	**PAPER NUMBER**
2624	

DATE MAILED: 03/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/075,108	PEDAIN ET AL.	
	Examiner	Art Unit	
	Patrick L. Edwards	2621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,13-20,22 and 23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,13-20,22 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The response received on 02-23-2006 has been placed in the file and was considered by the examiner. An action on the merits follows.

Response to Arguments

2. The arguments filed on 02-23-2006 have been fully considered. A response to these arguments is provided below.

Prior Art Rejections

Summary of Argument:

Respecting claims 22 and 23, applicant argues that the Kucharczyk reference does not read on the claims because "Kucharczyk discloses a method wherein drug delivery is monitored as it is being administered and/or after it has been administered to the patient."

Examiner's Response:

Applicant's arguments have been fully considered but are unpersuasive. It appears that applicant is reading limitations from the specification into the claims. This is improper (see MPEP 2111). Claims are given their broadest reasonable interpretation, and limitations from the specification are not to be read into the claims. Given this broadest reasonable interpretation, the Kucharczyk reference reads on the claim.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-8, 11, 13, and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Anderson et al. (US 2002/0168618)

As applied to claim 1, Anderson discloses planning administration of a substance into a patient (Anderson paragraph [0011]).

Anderson discloses capturing patient data (Anderson paragraph [0084]).

Anderson discloses performing the following, prior to positioning an infusion or withdrawal catheter: Using said patient data to plan an infusion of the substance into the patient by using a simulation of a planned infusion (See the Anderson reference generally—all of which is directed toward a simulation of medical procedures such as position an infusion or withdrawal catheter (see Anderson paragraph [0018], e.g.). All of these simulations use patient data (see Anderson paragraph [0084]).).

As applied to claim 11, Anderson discloses a computer program embodied on a computer readable medium operable to perform the method of claim 1 (See Figs. 1 and 3, for example).

As applied to claim 13, Anderson discloses a device that performs the method of claim 1 (See Anderson Fig. 2, for example).

As applied to claim 2, Anderson discloses that at least one infusion device is positioned using patient data (Anderson paragraph [0085]).

As applied to claim 3, Anderson discloses that the infusion device is positioned on the patient with respect to the infusion location (Anderson paragraph [0087]: The reference describes using a manequin for the simulation. Obviously, since this manequin is used for training purposes, the infusion device is positioned on the manequin where it is positioned on the actual human.).

As applied to claim 4, Anderson discloses that patient data are captured by means of x-ray, MRI, CT, or ultrasound (Anderson paragraph [0096]).

As applied to claims 5 and 6, Anderson discloses that patient parameters such as tissue structure, tissue density, blood flow and/or metabolic properties of said tissue is used as patient parameters for planning the infusion (Anderson paragraphs [0151]-[0152], e.g.).

As applied to claim 8, Anderson discloses that catheter parameters are used for planning the infusion (Anderson paragraph [0157]).

As applied to claim 14, Anderson discloses the required navigation system (see paragraph [0158] and the subsequent descriptive paragraphs).

5. Claims 22 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Kucharczyk et al. (USPN 6,026,316).

As applied to claim 22, Kucharczyk discloses a device for carrying out an infusion, comprising a verification device for comparing planned infusion data with actual infusion data (Kucharczyk Figure 7: The figure describes a device for carrying out infusion (i.e. drug delivery) that comprises a verification device for comparing planned infusion data (i.e. anatomic map of target tissue) with actual infusion data (i.e. drug delivery map).).

As applied to claim 23, Kucharczyk discloses correcting deviations between actual infusion data and planned infusion data (Kucharczyk Figure 7: The reference describes repeating drug delivery as necessary following the comparison between actual and planned infusion data. This act of repeating immediately follows the determination of efficacy of drug delivery (i.e. the comparison), and therefore corrects the deviations that were found in the "efficacy determination" section.).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 15, 16, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (US 2002/0168618).

As applied to claim 15, Anderson discloses performing the following, prior to positioning an infusion or withdrawal catheter: Using said patient data to plan an infusion of the substance into the patient by using a simulation of a planned infusion (See the Anderson reference generally—all of which is directed toward a simulation of medical procedures such as position an infusion or withdrawal catheter (see Anderson paragraph [0018], e.g.). All of these simulations use patient data (see Anderson paragraph [0084]).).

Regarding the further limitation of "executing the planned infusion," Anderson is mainly directed to the simulation of the infusion and not to the infusion itself. However, in the background section, Anderson explains that this simulation system is needed to assist physicians who later execute infusions (see pg. 1 of Anderson). As a result, It would have been obvious to one reasonably skilled in the art at the time of the invention to follow Anderson's suggestion, and perform this simulation before the execution of the infusion. This would have allowed for improved performance of the executed infusion because a simulation that is performed just prior to execution would allow for the physicians to be fully prepared to perform the operation..

As applied to claim 20, Anderson discloses a computer program embodied on a computer readable medium operable to perform the method of claim 15 (See Figs. 1 and 3, for example).

As applied to claim 16, Anderson discloses that the infusion is planned in accordance with a method wherein patient data are captured and the infusion to be carried out is planned using said patient data (Anderson paragraphs [151]-[152]).

The examiner would like to note that these claims likely could have been rejected under 35 USC 102, because the reference is arguably anticipatory. The rejections were made instead under 35 USC 103 to err on the safe side.

8. Claims 17-19 are rejected under 35 U.S.C 103(a) as being unpatentable over the combination of Anderson et al. (US 2002/0168618) and Raghavan et al. (USPN 6,549,803). The arguments as to the relevance of Anderson as applied in the parent claim is incorporated herein.

As applied to all of claims 17-19, the Anderson disclosure is directed more towards the infusion simulation or the planned infusion data, and is therefore not drawn towards the analysis of the actual infusion data. As a result, the Anderson reference is deficient to meet the limitations of comparing the actual and planned infusion data (claim 17) to determine the differences between the two (claim 18) in order to correct those differences (claim 19).

Raghavan, on the other hand, clearly discloses all of these steps (see Raghavan col. 14 line 63 – col. 15 line 64 in conjunction with Figure 7: See specifically col. 15 lines 32-64, which describes a comparison between the two, and then further describes that if the difference between the two is above a tolerance, that the difference should be corrected). It would have been obvious to one reasonably skilled in the art at the time of the invention to modify Anderson's simulation system by including a comparison of that simulation with actual data as taught by Raghavan. Such a modification would have allowed for a system that could enable computation to predict the results of particular administration strategies fast enough to that plans can be compared, and then an optimal plan could be chosen in a clinically acceptable time (Raghavan col. 4 lines 31 –50).

9. Claims 7, 9, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Anderson et al. (US 2002/0168618) and Lemelson (USPN 5,919,135). The arguments as to the relevance of Anderson as applied in the parent claim is incorporated herein.

As applied to claim 7, Anderson discloses using parameters for an infusion, but fails to expressly disclose using parameters that define the chemical, biological, and/or physical properties of the substance.

As applied to claim 9, Anderson discloses that the distribution of the substance is simulated based on patient parameters obtained from captured patient data and catheter parameters, but fails to expressly disclose that the distribution of the substance is based on a parameter of the substance.

As applied to claim 10, Anderson discloses that a target volume and/or distribution of the substance in the patient is pre-set, and that the catheter parameters are based on this preset target volume and distribution. Anderson fails to expressly disclose that the parameters of the substance are based on this preset target volume and distribution.

Thus, the same element is lacking from all of the above 3 claims—namely, the use of the substance itself as an infusion parameter. Anderson does not expressly disclose this. Lemelson, on the other hand, discloses an infusion modeling system that does make use of chemical, biological, and/or physical properties of the substance (e.g., at Lemelson col. 13 line 25 – col. 14 line 5). It would have been obvious to one reasonably skilled in the art at the time of the invention to modify Anderson by using the parameters of the infusing substance in the simulation of the

infusion. Such a modification would have allowed for an additional variable would have made the simulation more accurate.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- Merril et al. (WO 96/28800) – describes a simulation system for medical procedures such as a catheter infusion.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick L Edwards whose telephone number is (571) 272-7390. The examiner can normally be reached on 8:30am - 5:00pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Mancuso can be reached on (571) 272-7695. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patrick L Edwards Art Unit 2621

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ANDREW W. JOHNS
PRIMARY EXAMINER